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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,810	01/24/2002	Xianqiang Li	26757-709	4240

21971 7590 10/20/2003

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EXAMINER

BYRD, DEVON R

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 10/20/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/057,810	LI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	<i>File Copy</i>
	Devon R Byrd	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 January 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-46 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

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DETAILED ACTION

*STATUS OF THE CLAIMS*

CLAIMS 1-46 ARE PENDING IN THE PRESENT APPLICATION AND ARE SUBJECT TO RESTRICTION AND ELECTION OF SPECIES REQUIREMENTS.

*ELECTION/RESTRICTIONS*

RESTRICTION TO ONE OF THE FOLLOWING INVENTIONS IS REQUIRED UNDER 35 U.S.C.

121:

- I. CLAIMS 1-31, DRAWN TO A METHOD FOR IDENTIFYING MULTIPLE DIFFERENT TRANSCRIPTION FACTORS IN A CELL SAMPLE, CLASSIFIED IN CLASS 435, SUBCLASS 91.1.
- II. CLAIMS 32-38, DRAWN TO A METHOD FOR CHARACTERIZING A CELL TYPE OF A CELL SAMPLE, CLASSIFIED IN CLASS 435, SUBCLASS 70.1.
- III. CLAIMS 39-42, DRAWN TO A METHOD FOR DIAGNOSING A DISEASE STATE IN A CELL SAMPLE, CLASSIFIED IN CLASS 424.
- IV. CLAIMS 43-46, DRAWN TO A METHOD FOR SCREENING FOR TRANSCRIPTION FACTOR MODULATORS, CLASSIFIED IN CLASS 435, SUBCLASS 91.5.

THE INVENTIONS ARE DISTINCT, EACH FROM THE OTHER BECAUSE OF THE FOLLOWING REASONS:

RESTRICTION IS DEEMED PROPER BECAUSE CERTAIN OF THE ABOVE METHODS CONSTITUTE PATENTABLY DISTINCT INVENTIONS FOR THE FOLLOWING REASONS: GROUPS I-IV ARE DIRECTED TO METHODS THAT RECITE STRUCTURALLY AND FUNCTIONALLY DISTINCT ELEMENTS, ARE NOT REQUIRED FOR ONE ANOTHER, AND ACHIEVE DIFFERENT GOALS. THE CIS ELEMENT LIBRARIES OF GROUPS I-IV COMPRISE MOLECULES THAT DIFFER IN LENGTH AND NUCLEIC ACID CONTENT AND THUS

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CONSTITUTE PATENTABLY DISTINCT COMPOUNDS WHICH MAY POSSESS DIFFERENT PHYSICOCHEMICAL PROPERTIES AND/OR METHODS OF MANUFACTURE.

BECAUSE THESE INVENTIONS ARE DISTINCT FOR THE REASONS GIVEN ABOVE, AND

- A. HAVE ACQUIRED A SEPARATE STATUS IN THE ART AS SHOWN BY THEIR DIFFERENT CLASSIFICATION;
- B. HAVE DIFFERENT AND SEPARATELY BURDENSOME MANUAL AND/OR COMPUTER STRUCTURE, NAME, AND BIBLIOGRAPHICAL SEARCHES; AND,
- C. HAVE DIVERGENT SUBJECT MATTER, RESTRICTION FOR EXAMINATION PURPOSES AS INDICATED IS PROPER.

**FURTHER RESTRICTION:**

UPON SELECTION OF ANY OF THE GROUPS I-IV, APPLICANT MUST FURTHER ELECT A SPECIFIC SUBGENERIC COMPOSITION (E.G., ACTIVATED TRANSCRIPTION FACTORS, CIS ELEMENTS (E.G., AS DISCLOSED IN FIGURE 2 OF THE SPECIFICATION), A PROMOTER SEQUENCE 3' TO A CIS ELEMENT, A REPORTER SEQUENCE 3' TO A CIS ELEMENT (E.G., AS DISCLOSED IN FIGURE 2 OF THE SPECIFICATION)) FOR PROSECUTION ON THE MERITS.

APPLICANT IS ADVISED THAT THE REPLY TO THIS REQUIREMENT TO BE COMPLETE MUST INCLUDE AN ELECTION OF THE INVENTION TO BE EXAMINED EVEN THOUGH THE REQUIREMENT BE TRAVERSED (37 CFR 1.143).

APPLICANT IS REMINDED THAT UPON THE CANCELLATION OF CLAIMS TO A NON-ELECTED INVENTION, THE INVENTORSHIP MUST BE AMENDED IN COMPLIANCE WITH 37 CFR 1.48(B) IF ONE OR MORE OF THE CURRENTLY NAMED INVENTORS IS NO LONGER AN INVENTOR OF AT LEAST ONE CLAIM REMAINING IN THE APPLICATION. ANY AMENDMENT OF INVENTORSHIP MUST BE ACCOMPANIED BY A REQUEST UNDER 37 CFR 1.48(B) AND BY THE FEE REQUIRED UNDER 37 CFR 1.17(ii).

*ELECTION OF SPECIES (ALL GROUPS)*

CLAIMS 1, 32, 39, AND 43 ARE GENERIC TO A PLURALITY OF DISCLOSED PATENTABLY  
DISTINCT SPECIES COMPRISING:

1. IN VITRO METHODS VERSUS IN VIVO METHODS- SAID CLAIMS CURRENTLY READ ON  
BOTH,
2. A SPECIES OF CELL TYPES- SAID CLAIMS CURRENTLY READ ON AN ESSENTIALLY  
INFINITE NUMBER OF CELL TYPES
3. A BIOLOGIC SOURCE OF A CELL SAMPLE- SAID CLAIMS CURRENTLY READ ON AN  
ESSENTIALLY INFINITE NUMBER OF ORGANISMS CAPABLE OF PROVIDING SOURCE  
MATERIAL FOR A CELL SAMPLE
4. A CLASS OF VARIABLE SEQUENCE THAT VARIES WITHIN THE LIBRARY- SAID CLAIMS  
CURRENTLY READ ON AN INFINITE NUMBER OF CLASSES OF CHEMICAL COMPOUNDS
5. A SINGLE COMPOUND FROM THE ELECTED CLASS OF (4)- SAID CLAIMS CURRENTLY  
READ ON AN INFINITE NUMBER OF CHEMICAL COMPOUNDS OF ANY CLASS.

*FURTHER ELECTION OF SPECIES*

THIS APPLICATION CONTAINS CLAIMS DIRECTED TO THE FOLLOWING PATENTABLY DISTINCT  
SPECIES OF THE CLAIMED INVENTION:

- A) A NUMBER OF DIFFERENT CIS ELEMENTS (E.G., 10, 20, 50, 100; SEE CLAIMS  
2-10)
- B) A NUMBER OF COPIES OF CIS ELEMENTS (E.G., 2, 3, 4; SEE CLAIMS 6-8)
- C) A CIS ELEMENT LENGTH (E.G., 5-100, 5-75, 5-50; SEE CLAIMS 9-11)

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- D) A LOWER LIMIT ON VARIABLE SEQUENCE LENGTH OF THE REPORTER (E.G., 15, 25, 50 BASE PAIRS; SEE CLAIMS 12-17)
- E) A SPECIES OF MAMMAL OR MAMMALIAN CELL LINE (E.G., COS CELL LINES, HeLa CELLS, MYELOMA CELL LINES, AND CHO CELL LINES; SEE SPECIFICATION P 19, LNS 10-12) AS A SOURCE FOR A CELL SAMPLE (CLAIM 18)
- F) A NUMBER OF DIFFERENT REPORTER SEQUENCES (E.G., 10, 20, 50; SEE CLAIMS 21-23)
- G) A 5' PRIMING SEQUENCE (SEE CLAIM 25)
- H) A 3' PRIMING SEQUENCE (SEE CLAIM 25)
- I) A LIBRARY OF HYBRIDIZATION PROBES (SEE CLAIM 27)
- J) A REPORTER PROTEIN (SEE CLAIM 29)
- K) A LIBRARY OF ANTIBODIES (SEE CLAIM 30)
- L) A TYPE OF DISEASED CELL (SEE CLAIM 34)
- M) A NUMBER OF DIFFERENT REPORTER SEQUENCES (E.G., 10, 20, 50; SEE CLAIMS 36-38, 40-42, AND 44-46)
- N) A DISEASE STATE IN A CELL SAMPLE (SEE CLAIM 39)

THE SPECIES MENTIONED ABOVE HAVE DIFFERENT AND SEPARATELY BURDENSOME MANUAL AND/OR COMPUTER STRUCTURE, NAME, AND BIBLIOGRAPHICAL SEARCHES; AND HAVE DIVERGENT SUBJECT MATTER. APPLICANT IS REQUIRED UNDER 35 U.S.C. 121 TO ELECT A SINGLE DISCLOSED SPECIES FOR PROSECUTION ON THE MERITS TO WHICH THE CLAIMS SHALL BE RESTRICTED IF NO GENERIC CLAIM IS FINALLY HELD TO BE ALLOWABLE, EVEN THOUGH THIS REQUIREMENT IS TRAVERSED.

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APPLICANT IS ADVISED THAT A REPLY TO THIS REQUIREMENT MUST INCLUDE AN IDENTIFICATION OF THE SPECIES THAT IS ELECTED CONSONANT WITH THIS REQUIREMENT, AND A LISTING OF ALL CLAIMS READABLE THEREON, INCLUDING ANY CLAIMS SUBSEQUENTLY ADDED. AN ARGUMENT THAT A CLAIM IS ALLOWABLE OR THAT ALL CLAIMS ARE GENERIC IS CONSIDERED NONRESPONSIVE UNLESS ACCOMPANIED BY AN ELECTION.

UPON THE ALLOWANCE OF A GENERIC CLAIM, APPLICANT WILL BE ENTITLED TO CONSIDERATION OF CLAIMS TO ADDITIONAL SPECIES WHICH ARE WRITTEN IN DEPENDENT FORM OR OTHERWISE INCLUDE ALL THE LIMITATIONS OF AN ALLOWED GENERIC CLAIM AS PROVIDED BY 37 CFR 1.141. IF CLAIMS ARE ADDED AFTER THE ELECTION, APPLICANT MUST INDICATE WHICH ARE READABLE UPON THE ELECTED SPECIES. MPEP § 809.02(A).

SHOULD APPLICANT TRAVERSE ON THE GROUND THAT THE SPECIES ARE NOT PATENTABLY DISTINCT, APPLICANT SHOULD SUBMIT EVIDENCE OR IDENTIFY SUCH EVIDENCE NOW OF RECORD SHOWING THE SPECIES TO BE OBVIOUS VARIANTS OR CLEARLY ADMIT ON THE RECORD THAT THIS IS THE CASE. IN EITHER INSTANCE, IF THE EXAMINER FINDS ONE OF THE INVENTIONS UNPATENTABLE OVER THE PRIOR ART, THE EVIDENCE OR ADMISSION MAY BE USED IN A REJECTION UNDER 35 U.S.C. 103(A) OF THE OTHER INVENTION.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DEVON R BYRD WHOSE TELEPHONE NUMBER IS 703-305-0159. THE EXAMINER CAN NORMALLY BE REACHED ON MON-FRI 8A-5P.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, ANDREW WANG CAN BE REACHED ON 703-306-2317. THE FAX PHONE NUMBER FOR THE ORGANIZATION WHERE THIS APPLICATION OR PROCEEDING IS ASSIGNED IS (703) 872-9306.

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ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR  
PROCEEDING SHOULD BE DIRECTED TO THE RECEPTIONIST WHOSE TELEPHONE NUMBER IS 703-  
308-1235.

DB

OCTOBER 14, 2003

RECEIVED 10/14/03  
